

to investigate the safety and efficacy of the BVS in a real world setting, waiving obligatory IVUS or OCT guidance.

**Methods:** Consecutive patients with ischemic heart disease and de novo native coronary artery lesions were enrolled at 6 German centers in the prospective, observational registry. During the first 6 months of enrollment, only 3.0 x 18 mm BVS were available. From then onwards, 2.5 mm, 3.0 mm, and 3.5 mm BVS of different length were also available. BVS sizing was based on visual estimate of the lesions.

**Results:** A total of 183 patients were treated with BVS. A complex ACC/AHA lesion morphology of B2 or C was seen in 128 (64.7%) lesions. Compared to QCA, visual estimate overestimated the baseline reference vessel diameter (RVD) by  $0.5 \pm 0.5$  mm and the diameter stenosis (DS) by  $13.2 \pm 16.5$  %. Nevertheless, the final minimal lumen diameter (MLD) closely matched the baseline RVD. Diameter stenosis was  $64.6 \pm 15.1$  % at baseline and improved to a residual DS of  $16.1 \pm 7.7$  %. Acute gain of MLD was  $1.54 \pm 0.51$  mm. A BVS-RVD mismatch resulted in an optimal MLD but an overexpanded RVD in case of 3.0 BVS for < 2.5 mm vessels, whereas in 3.3 mm vessels final MLD fell below the RVD. Final RVD exceeded the BVS expansion limit in 20 (10.1%) lesions. No periprocedural dissection was reported from the core laboratory. At 12 months, 1 (0.5%) death due to gastrointestinal bleeding under dual antiplatelet therapy and 3 (1.6%) myocardial infarctions, caused by non-target vessel failure, had occurred. Target lesion revascularization had to be carried out in 5 patients (2.8%).

**Conclusions:** Visual overestimation of baseline RVD resulted in an optimal final MLD. BVS-RVD mismatch may lead to an inappropriate RVD or MLD. Acute gain and frequency of MACE were in agreement with previous BVS and DES studies.

# TCT-635

## ACUTE AND MID-TERM CLINICAL OUTCOMES OF THE EVEROLIMUS-ELUTING BIORESORBABLE VASCULAR SCAFFOLDS IN AN ALL-COMER COHORT

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**Background:** Bioresorbable vascular scaffold (BVS) heralded as the fourth revolution in interventional cardiology. Previous studies demonstrated the safety and efficacy of bioresorbable everolimus-eluting scaffolds in selected group of patients. However, limited data are available on the clinical use and outcomes of BVS in the real life setting.

**Methods:** Between November 2012 and April 2014, 89 consecutive patients were treated with BVS and enrolled in a prospective single center registry. The indication of BVS was left to the discretion of the operator.

**Results:** Mean age was  $59 \pm 11$  years old and males in 69%. They had hypertension in 56%, dyslipidemia in 52%, and diabetes in 29%, smokers in 48% and known coronary artery disease in 20%. Clinical presentation was acute coronary syndrome in 70 % of patients. Patients had a single vessel disease in 66% and the left ventricular ejection fraction (LVEF) was  $58 \pm 8$  %. One hundred sixteen lesions were treated (30% were type A, 62% type B and 8% type C). Average used BVS/patient was  $1.29 \pm 0.59$ . Mean BVS diameter and length were  $3.1 \pm 0.35$  mm and  $22 \pm 5.25$  mm respectively. Procedural success and device success was 100%. The median follow-up was 199 days [29-365]. The in-hospital MACE rate was low (1%; 1 case of acute definite BVS thrombosis). The cumulative mid term MACE rate was 5 % (all cause mortality was 1% (probable BVS thrombosis); MI 1% (definite subacute BVS thrombosis) and 3% TLR (3 cases of in-BVS restenosis)).

**Conclusions:** In this all-comer cohort, BVS was mainly reserved to non-complex cases and had a high acute procedural success with good mid term clinical outcomes. Ongoing studies with long-term follow-up will confirm the safety and efficacy of BVS in the treatment of more challenging cases.

# TCT-636

## Use Of Optical Coherence Tomography To Study The Role Of Non-Compliant Balloon Post-Dilation In Optimization Of Bioresorbable Vascular Scaffolds

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**Background:** The effect of mandatory non-compliant balloon (NCB) post-dilation on bioresorbable vascular scaffolds (BVS) is not known. We sought to

assess the impact of NCB post-dilation on optimizing BVS by using Optical coherence tomography (OCT). We hypothesized that systematic post-dilation to high pressures would significantly improve expansion and reduce malapposition.

**Methods:** In this ethics approved study we enrolled 18 patients. Per protocol, mandatory pre-dilation was followed by intracoronary nitroglycerin and initial OCT assessment. BVS was deployed at  $\geq 14$  atm for 30 seconds and NCB post-dilation performed at  $\geq 16$  atm for a minimum of 30 seconds. OCT was repeated after BVS deployment and after NCB post-dilation. All OCT images were analyzed offline. Pre and post NCB post-dilation, the scaffold was analyzed for minimum and mean diameters, and minimum scaffold cross-sectional area. Optimal expansion of BVS was defined as minimum scaffold area of  $\geq 80$  % of reference vessel area. The length of the scaffold was also assessed for clinically relevant incomplete scaffold apposition (ISA) defined as incomplete contact of BVS struts with vessel wall for a distance of greater than the strut thickness of 0.15 mm, over at least 25 % of the scaffold circumference, and over a scaffold length of at least 1 mm.

**Results:** 22 lesions in 18 patients were analyzed. Mean patient age was 57.5 yrs and 83% were male. The indication was stable angina in 83% cases. Using OCT, the reference vessel diameter at baseline was 2.95 mm. The mean BVS diameter used was 2.9 mm and the mean diameter of NCB used was 3.5 mm. After NCB post-dilation, the minimum scaffold diameter increased by a mean of 0.19 mm, the mean scaffold diameter increased by a mean of 0.20 mm and optimal expansion increased from 59 % to 86.4 % of cases ( $p < 0.0001$ ). After NCB use, clinically relevant ISA decreased from 5 to 3 cases.

**Conclusions:** Non-compliant balloon post-dilation of BVS significantly increased the minimum and mean scaffold diameter. The rate of optimal scaffold expansion increased by 27%, and the incidence of clinically relevant incomplete scaffold apposition decreased by 40%.

# TCT-637

## Analysis of Quality of Life Decrements Associated with Changes in Angina Status in the ABSORB II Trial: First Randomized Comparison Between the Absorb™ Everolimus Eluting Bioresorbable Vascular Scaffold and the XIENCE™ Everolimus Eluting Stent

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**Background:** Patient reported outcomes (PROs) are increasingly recognized as important clinical trial endpoints that provide direct information about health status and help guide clinical and economic decisions. Prior studies have reported quality of life (QoL) decrements attributable to changes in angina status. The objective of this study was to assess the impact of changes in angina status following percutaneous coronary intervention (PCI) on QoL in ABSORB II, a randomized, controlled, multicenter trial that compared the safety and efficacy of the Absorb™ Bioresorbable Vascular Scaffold (Abbott Vascular, Santa Clara, CA) to the XIENCE™ Everolimus Eluting Stent (Abbott Vascular, Santa Clara, CA).

**Methods:** In the ABSORB II trial, we obtained disease-specific QoL and general health status information from patients using validated PRO instruments administered pre-intervention, at 6 months, and 1 year post-discharge. We examined the timing of changes in angina status in relation to the assessment date of the EuroQol-5 Dimension Questionnaire (EQ-5D). We compared means and confidence intervals of subjects with changes in angina status within 1 month, 1-3 months, and greater than 3 months prior to assessment. A similar analysis was conducted for the Seattle Angina Questionnaire (SAQ). Multivariate analysis was performed to control for observable patient characteristics that might influence QoL.

**Results:** The ABSORB II trial enrolled 501 patients at 46 sites in Europe and New Zealand and randomized in a 2:1 ratio to Absorb™ BVS (N=335) or XIENCE™ (N=166). We will present results of the univariate and multivariate analyses in the ABSORB II intent-to-treat population.

**Conclusions:** Research to date indicates that changes in angina status are independently associated with reduced QoL. Results from the ABSORB II trial will provide current evidence of the impact of changes in angina status on QoL following PCI with Absorb™ and XIENCE™.